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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/600,061	06/20/2003	Cesar Z. Lina	VAC.567.1.US	5656

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LEGAL DEPARTMENT INTELLECTUAL PROPERTY
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EXAMINER	
HAND, MELANIE JO	

ART UNIT	PAPER NUMBER
3761	

DATE MAILED: 07/13/2006

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	10/600,061	LINA ET AL.	
	Examiner	Art Unit	
	Melanie J. Hand	3761	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *01 May 2006*.

2a)☒ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-19* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1-19* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date *5/22/06*.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: _____.

DETAILED ACTION

Response to Arguments

Applicant's arguments filed May 1, 2006 with respect to claims 1-9 have been fully considered but they are not persuasive. With respect to applicant's argument that Examiner did not address the limitation of polyether foam, Examiner reminds applicant that the claim language of claim 4 reads "from a material selected from the group consisting of..." which in its interpretation allows Examiner to choose one or the other for claim interpretation, not both.

With respect to the remainder of applicant's argument regarding the lack of motivation to combine the prior art of Hunt and McRae, Examiner is unclear as to the relevance of this assertion to the claim language. Applicant cites the perceived lack of desirability in compressing the dressing of McRae and therefore that, since McRae teaches away from compression, such wound dressing cannot be combined with the prior art of Hunt. Nowhere in applicant's claim language is there any reference to compression or lack thereof that is required. Further, Examiner disagrees that suction applied to McRae would destroy the dressing. Suction would compress the dressing of McRae at best, only momentarily, and would not destroy the function of the dressing of McRae as asserted by applicant. Still further, McRae teaches that the pressure that can be applied is up to 200 psi before the scenario set forth by applicant (i.e. formation of an occlusive dressing) occurs, and the capacity or suction flow applied by the pump taught by Hunt is not taught by Hunt. In fact, the device taught by Hunt is a portable device and thus a pump that provides a suction pressure above the 200 psi limit taught by McRae would not be capable of being integrated therein. Thus the function of the dressing of McRae cannot be destroyed. ('855, Col. 4, lines 66-68)

Applicant's arguments with respect to claims 10-17 have been considered but are moot in view of the new ground(s) of rejection prompted by applicant's amendment to claim 10. Examiner notes that Hunt teaches a porous wound dressing pad that is adapted to communicate with a negative pressure source in the form of a suction pump and therefore the combined teaching of Hunt and McRae renders applicant's amended claim 10 unpatentable. With respect to new claims 18 and 19, a sprayable substance is necessarily at least partially comprised of a propellant gas as taught by Coffee ('129, Col. 1, lines 13-20), as the gas makes the act of spraying onto a substrate possible.

Information Disclosure Statement

The information disclosure statement (IDS) submitted on May 22, 2006 was filed after the mailing date of the Application on June 20, 2003. The submission is in compliance with the provisions of 37 CFR 1.97. Accordingly, the information disclosure statement is being considered by the examiner.

Claim Rejections - 35 USC § 103

The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action.

Claims 1-6, 9, 10 and 12-17 are rejected under 35 U.S.C. 103(a) as being unpatentable over Hunt ('982) in view of McRae et al (U.S. Patent No. 3, 978,855).

With respect to **Claims 1,10:** Hunt teaches a porous pad 102 (Fig. 1) that is permeable to liquids and that is held in place by a surgical drape 701 with adhesive providing a seal around said pad and wound (Col. 5, lines 26-29). Hunt also teaches a vacuum canister 100 for

collecting drainage fluid that is sucked from the wound via a suction pump 6 (negative pressure) and connected to the porous pad through a drainage tube 101 (Fig. 1). Hunt does not teach an outer surface with pores of a first size contacting the wound or a pad with an inner body with pores of a second average size. McRae teaches a wound dressing comprised of open-celled polyurethane foam (Col. 4, lines 53-58) McRae teaches that the polyurethane dressing is compressed to cause cells near at least one surface of said foam to collapse either temporarily or permanently, decreasing their pore size and thus creating a microporous skin on at least that particular surface area, leaving the cells in areas remote from said skin at their original size (now larger compared to the pores at the skin surface). McRae teaches that said first and second pore sizes are to promote sufficient wicking and absorption at the microporous skin surface that is adjacent the wound surface and the larger size is to allow ready absorption while still being small enough to be capable of prohibiting excess exudate absorbed by the microporous skin to pass into the remote region. Therefore it would be obvious to one of ordinary skill in the art to modify the dressing of Hunt by compressing said dressing so as to collapse some of the pores at a surface to a first size to create a microporous skin and keep the remote pores at a second larger pore size as taught by McRae.

With respect to **Claim 2:** Hunt teaches that a hole is cut through all layers of the surgical drape 701 holding the dressing in place to accommodate the drainage tube (Col. 5, lines 30-33).

With respect to **Claim 3:** By virtue of having pores in a dressing that are capable of being drained of exudates via negative pressure from a suction pump, the pores of a second average size in the dressing of the combined teaching of Hunt and McRae are considered herein to be vacuum-compatible.

With respect to **Claim 4:** Hunt teaches that the dressing is a pad of polyurethane foam (Col. 5, lines 49-51).

With respect to **Claim 5:** Hunt does not teach pores having a first size. McRae teaches that pores in the microporous skin area have a diameter in the range of 0.2-200 microns. (Col. 4, lines 42-45, 52-57) McRae teaches that said first and second pore sizes are to promote sufficient wicking and absorption at the microporous skin surface that is adjacent the wound surface and the larger size is to allow ready absorption while still being small enough to be capable of prohibiting excess exudate absorbed by the microporous skin to pass into the remote region. Therefore it would be obvious to one of ordinary skill in the art to modify the dressing of Hunt by compressing said dressing so as to collapse some of the pores at a surface to a first size to create a microporous skin and keep the remote pores at a second larger pore size as taught by McRae.

With respect to **Claim 6:** Hunt teaches that the surgical drape is comprised of polyurethane film, understood in the art to be an elastomeric material. (Col. 8, lines 27-28)

With respect to **Claim 9:** Hunt does not teach forming pores by placing said dressing pad in a liquid coating material. McRae teaches a wetting agent (liquid coating material) that an open-celled polyurethane foam is inserted into to a desired amount to achieve a particular pore size. (Col. 6, lines 28-42) McRae teaches that said first and second pore sizes are to promote sufficient wicking and absorption at the microporous skin surface that is adjacent the wound

surface and the larger size is to allow ready absorption while still being small enough to be capable of prohibiting excess exudate absorbed by the microporous skin to pass into the remote region. Therefore it would be obvious to one of ordinary skill in the art to modify the dressing of Hunt by compressing said dressing so as to collapse some of the pores at a surface to a first size to create a microporous skin and keep the remote pores at a second larger pore size as taught by McRae.

With respect to **Claims 12 and 13:** McRae teaches that said microporous skin is formed from the original foam material by compression and not by the addition of another structural entity or chemical compound, therefore the dressing of the combined teaching of Hunt and McRae is a unitary assembly.

With respect to **Claims 14 and 15:** Hunt teaches that the seal around the wound site is substantially airtight (Col. 6, line 18).

With respect to **Claim 16:** Hunt teaches one filter interposed between a suction pump and a vacuum canister (Col. 6, lines 57-59).

With respect to **Claim 17:** Hunt teaches that a suction pump is adapted to draw liquid from a sealed porous pad through a drainage conduit and into a vacuum canister (Col. 6, lines 23-25).

Claim 7 is rejected under 35 U.S.C. 103(a) as being unpatentable over Hunt et al (U.S. Patent No. 6,142,982) in view of McRae et al ('855) as applied to claims 1-6, 9, 10 and 12-17 above, and further in view of Shioya et al (U.S. Patent No. 4,997,425).

With respect to **Claim 7:** The combined teaching of Hunt and McRae does not teach the addition of an antimicrobial agent to said wound dressing. Shioya teaches the addition of an antimicrobial agent to the porous wound dressing (Col. 6, line 65-Col. 7, line 2). The benefits of an antimicrobial agent are well known and applicable to devices contacting a wound surface, therefore it would be obvious to someone of ordinary skill in the art to modify the dressing of the combined teaching of Hunt and McRae by adding an antimicrobial agent as taught by Shioya.

Claims 8, 11, 18 and 19 are rejected under 35 U.S.C. 103(a) as being unpatentable over Hunt et al (U.S. Patent No. 6,142,982) in view of McRae et al ('855) as applied to claims 1-7, 9, 10 and 12-17 above, and further in view of Coffee (U.S. Patent No. 6,252,129)

With respect to **Claims 8 and 11:** The combined teaching of Hunt and McRae does not teach a foam dressing that may be released from a spray nozzle and deposited directly into the wound cavity, subsequently conforming to the shape of the wound cavity. Coffee teaches spraying a nontoxic polymeric flexible foam deposit into a wound to form a cavity wound dressing, with the dressing conforming to the contours of a cavity wound ('129, Col. 13, lines 52-55). It would be obvious to further modify the wound dressing of the combined teaching of Hunt and McRae to be able to be sprayed directly onto the wound wherein the dressing is a foam material that conforms to the shape of the wound as these spray devices are known, as taught by Coffee ('129, Col. 1, lines 14-17).

With respect to **Claims 18,19:** Coffee teaches that these sprayable substances for treating wounds are known and require a propellant gas to be dispersed onto a substrate, therefore it

would be obvious to one of ordinary skill in the art to provide propellant gas with the nontoxic chemical foam substance to ensure the proper application of said substance to the wound to create a properly fitting foam dressing. (Col. 1, lines 13-20)

Conclusion

Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Melanie J. Hand whose telephone number is 571-272-6464. The examiner can normally be reached on Mon-Thurs 8:00-5:30, alternate Fridays 8:00-4:30.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Tatyana Zalukaeva can be reached on 571-272-1115. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

Melanie J Hand
Examiner
Art Unit 3761

MJH

TATYANA ZALUKAEVA
SUPERVISORY PRIMARY EXAMINER